UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

BAYER SCHERING PHARMA AG, *et al.*,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Defendants.

Case No. 2:07-CV-01472-KJD-GWF
2:08-CV-00995-KJD-GWF

ORDER

Presently before the Court is Plaintiffs' Motion to Reset the Effective Date of the FDA's approval for the Defendants to Market Generic YAZ® (#339). Defendants filed a response in opposition (#348) to which Plaintiffs replied (#349).

I. Facts and Procedural History

Bayer has marketed its oral contraceptive YAZ® since March 2006. In 2007, Watson filed an ANDA to market a generic version of YAZ®. On November 5, 2007, Bayer filed suit against Watson alleging that Watson's ANDA constituted an act of infringement of the '564 patent under 35 U.S.C. § 271(e)(2). Bayer sought damages, injunctive relief, and an order setting the effective date of the FDA's approval of Watson's ANDA as no earlier than the expiration date of the '564 patent. See Doc. 1, 11/5/2007 Watson Complaint at 6-9. In 2008, Sandoz filed an ANDA to market its own

generic version of YAZ®. On August 1, 2008, Bayer filed suit against Sandoz alleging that its ANDA constituted an act of infringement of the '564 patent under 35 U.S.C. § 271(e)(2) and seeking the same relief sought from Watson. See 2:08-cv-00995-KJD-GWF, Dkt. 1, 8/1/2008 Sandoz Complaint 4-7. The Court consolidated both cases on November 4, 2008. See Doc. 43, 11/4/2008 Consolidation Order.

Upon the filing of each lawsuit, a stay commenced under 21 U.S.C. § 355(c)(3)(C) preventing the FDA from approving either Watson's or Sandoz's respective ANDAs until the expiration of thirty months or the resolution of the litigation on the merits. If the litigation lasted longer than thirty months, the FDA could approve the ANDA, and either generic applicant could then market its generic product at the risk of incurring damages for infringing sales if this Court found the '564 patent valid, infringed, and enforceable.

The thirty-month stays covering Watson's and Sandoz's respective ANDAs have both expired. The FDA approved Sandoz's generic YAZ® product in May 2011, and Sandoz launched its generic YAZ® product called Loryna® soon thereafter. See Bayer's Motion to Reset the Effective Date, Doc. No. 339, Ex. 1, 5/4/2011 Sandoz Press Release. Likewise, the FDA approved Watson's generic YAZ® product in November 2011, and Watson launched its own generic YAZ® product Vestura™ in January 2012. See Id., Ex. 2, 11/29/2011 Watson FDA Approval Press Release; Ex. 3, 1/18/2012 Watson Vestura™ Launch Press Release.

On March 30, 2012, this Court granted Bayer's motion for summary judgment of nonobviousness, finding that the '564 patent was both valid and enforceable against Watson and Sandoz. See Doc. 333, 3/30/2012 Order. The Court also granted Bayer's motion for summary judgment of no inequitable conduct. See Doc. 334, 3/30/2012 Order. Because the parties had already stipulated to Watson's and Sandoz's infringement of the '564 patent, the Clerk entered judgment in favor of Bayer and against Watson and Sandoz in these consolidated cases. See Doc. 336, 3/30/2012 Judgment in a Civil Case; see also Doc. 333, Order at 5.

II. Analysis

Under Hatch-Waxman, upon a finding that an ANDA-filer has infringed a valid patent, the Court shall order that the effective date of the FDA's approval of the ANDA be no earlier than the expiration date of the patent-in-suit. 35 U.S.C. § 271(e)(4)(A). If the FDA has already approved the ANDA, the trial court resets the effective date of approval until after the expiration of the infringed patent. Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1366 (Fed. Cir. 2008).

Despite Defendants' arguments to the contrary, the plain language of 35 U.S.C. § 271(e)(4)(A) provides for the resetting of the FDA's approval of Watson's and Sandoz's applications to market their respective generic YAZ® products. Upon a showing of an ANDA-filer's infringement of a valid and enforceable patent:

> the court ***shall order*** the effective date of any approval of the drug . . . product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

35 U.S.C. § 271(e)(4)(A) (emphasis added). This section makes no exception if the FDA has already approved the applicant's ANDA prior to the court's finding regarding infringement, validity, and enforceability. Courts that have dealt with a post-approval infringement finding have not imposed such an exception, resetting FDA approval even if the FDA has approved the ANDA and the product is on the market. See In re Omeprazole Patent Litigation, 536 F.3d 1361, 1367-68 (Fed. Cir. 2008); Ortho-McNeil Pharm., Inc., 520 F.3d at 1366; Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc., No. 04-1689, 2007 WL 869545, at *2 (D.N.J. Mar. 20, 2007) aff'd in part sub nom. Ortho-McNeil Pharm., Inc., 520 F.3d 1358 ("[T]he plain language here shows that Congress envisioned the factual scenario in which the ANDA had been approved, and intended that the district court then change the effective date"); Alza Corp. v. Mylan Labs., Inc., 310 F. Supp. 2d 610, 637 (D. Vt. 2004) ("Because infringement has occurred, the effective date of any approval of Mylan's ANDA product shall be no earlier than the date of the expiration of the '580 patent family").

Hatch-Waxman's legislative history confirms this result. Following a finding of infringement of a valid patent "the [court's] order would mandate a change in the effective date" of an approved

ANDA. H.R. REP. NO. 98-857(I), at 46 (1984), *reprinted* in 1984 U.S.C.C.A.N. 2647, 2679, 1984 WL 37416, at 31. And "if the infringing party has begun commercial marketing of the drug," "the FDA would be mandated to change the effective date of the approved ANDA to the expiration date of the infringed patent." Id.; Ortho-McNeil Pharm., Inc., 520 F.3d at 1366. The legislative history describes how the FDA operates in practice. See Plaintiff's Motion to Reset, Ex. 4, 6/22/2004 Letter from FDA to Mylan Technologies, Inc. at 1 (FDA "hereby rescinds the final approval of [generic's] ANDA" in light of district court's decision finding infringement and validity); see also Mylan Laboratories, Inc. v. Thompson, 389 F.3d 1272, 1277 (D.C. Cir. 2004) ("FDA concluded that the Vermont district court's order that 'the effective date of any approval of Mylan's ANDA product shall be no earlier than the date of expiration of the '580 patent family[]' . . . transformed Mylan's ANDA approval into 'an approval with a delayed effective date,' which 'is a tentative approval that cannot be made effective until FDA issues a letter granting final effective approval'").

Therefore, the Court orders that the effective date of the FDA's approval of Watson's and Sandoz's YAZ® ANDAs be reset until no earlier than June 30, 2014.

III. Conclusion

Accordingly, IT IS HEREBY ORDERED that Plaintiffs' Motion to Reset the Effective Date of the FDA's approval for the Defendants to Market Generic YAZ® (#339) is **GRANTED**;

IT IS FURTHER ORDERED that the effective date of the FDA's approval of Watson's and Sandoz's YAZ® ANDAs be reset until no earlier than June 30, 2014;

IT IS FURTHER ORDERED that Plaintiffs shall serve a copy of this order on the FDA.

DATED this 11th day of February 2013.

Kent J. Dawson
United States District Judge